UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,363	04/24/2001	Lawrence L. Labuda	4785.2US	6854

24247 7590 09/12/2005

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
SNAY, JEFFREY R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,363	LABUDA ET AL.	
	Examiner	Art Unit	
	Jeffrey R. Snay	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 24-30 recites a structural limitation, the definition of which is dependent upon a particular assembly of the transducer to a particular respiratory flow component. Since no flow component is recited as an element of the claims, this structural definition is ambiguous.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-10, 13-15, and 17-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al ('658) in view of Knodle et al ('720).

Stanley et al disclose a transducer for measuring oxygen in an airway breathing tube which comprises, referring to Figure 2, a light source (27), photodiode detector (28) and a luminescent oxygen sensor film (25). In operation, the sensor film is illuminated by the light source so as to excite fluorescent emission. The fluorescence is quenched quantitatively by oxygen present in the tube (14), and is measured by the detector. The transducer of Stanley et al differs from the claimed invention in that it fails to specify that it is removably securable to the breathing tube. However, Knodle et al disclose a similar optical sensor transducer for measuring carbon dioxide in a breathing tube. Knodle et al specifically disclose the transducer as being removably securable to breathing tubes (column 11, lines 34-45). It would have been obvious to one of ordinary skill in the art to

removably secure the transducer of Stanley et al to an associated breathing to in order to facilitate replacement thereof, as per the teaching of Knodle et al.

Regarding instant claim 2, Stanley et al provide a processor in the form of an amplifier and recorder in communication with the detector (Figure 1). Regarding instant claim 3, see Stanley et al at column 3, lines 16-18). Regarding instant claim 5, see Figure 4 of Stanley et al recognizing a non-linear response over a broad range of oxygen concentrations. As such, it would have been obvious to one of ordinary skill to apply a different mathematical processing to lower range concentrations as compared with higher range concentrations. Regarding instant claims 8 and 9, see Stanley et al at column 3, lines 12-15). Regarding instant claim 10, Stanley et al teach a calibration mechanism at column 5, lines 59 et seq. Stanley et al further teach excitation bands that encompass the visible spectrum (column 3, lines 12-15), and the particular wavelengths presently claimed.

Regarding instant claims 17-19, it is noted that while Stanley et al teach measurement of oxygen in a breathing tube, Knodle et al teach optical measurement of carbon dioxide in a breathing tube. Knodle et al teach such detection utilizing an infrared source. Thus, it would have been obvious to one of ordinary skill in the art to modify the transducer of Stanley et al to further include an infrared light source to enable detection of both oxygen and carbon dioxide.

Regarding instant claims 20-23, see optical filters (16 and 17) disclosed by Stanley et al in Figure 2. Regarding instant claims 24-30, see Stanley et al at the paragraph bridging columns 4 and 5, recognizing sensor susceptability to temperature

variations. In view of such recognition, it would have been obvious to one of ordinary skill in the art to modify the device of Stanley et al to include a temperature regulation device, in order to maintain the sensing film at a desired, optimal operating temperature.

Regarding instant claims 31-34, it is noted that the presently claimed features are clearly provided by the structure depicted by Stanley et al in Figures 1 and 2.

7. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Yafuso et al ('172).

The transducer of Stanley et al further differs in that it fails to provide a beam divider and reference detector. However, Yafuso et al teach such a structure in an optical detector for the purpose of accomodating variations in the excitation light. It would have been obvious to one of ordinary skill in the art to so modify the transducer of Stanley et al in order to attain the known benefits thereof, as per the teaching of Yafuso et al.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Hauenstein et al ('727).

Hauenstein et al disclose an optical sensor for determination of oxygen through fluorescence quenching. Hauenstein et al further teach that a signal to noise ratio is enhanced by use of a pulsed excitation signal. It would have been obvious to one of

ordinary skill in the art to so modify the transducer of Stanley et al in order to attain the known benefits thereof, as per the teaching of Hauenstein et al.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as background information related to applicant's field of endeavor.

Response to Arguments

10. Applicant's arguments filed 06-20-05 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, applicant argues that the transducer of Knodle operates in a manner which is not compatible with the device of Stanley because Knodle uses different wavelengths and would not function with a tube coated with luminescent material. However, the teaching of Knodle is relied upon only to establish as known the ability and desirability to construct the detection mechanism as a separable element from the detected airway tube. One of ordinary skill in the art would have recognized this feature of replaceability as analogously desirable in the device of Stanley, and would have been readily capable of constructing the light source and detector of Stanley as a removable transducer, in light of the guidance of Knodle et al. The rejection does

not assert that one of ordinary skill would simply apply the actual transducer of Knodle to the luminescent coated tube of Stanley.

With respect to the rejection under 35 USC 112, applicant argues that one of ordinary skill would know what a "respirator flow component" is. This argument fails to address the rejection. The ambiguity in the claims stems from the fact that each of claims 24-30 recites a structural limitation, the definition of which is dependent upon a particular assembly of the transducer to a particular respiratory flow component. Since no flow component is recited as an element of the claims, this structural definition is ambiguous.

11. Applicant's remarks further indicate that Information Disclosure Statements were filed on 04/24/01, 06/21/01 and 09/23/02. No such Disclosure Statements have been received in the application file.

12. Applicant's remarks further indicate that a preliminary amendment was filed on 07/30/01. No such amendment has been received in the application file.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

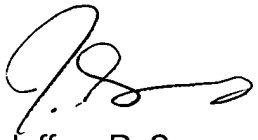
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey R. Snay
Primary Examiner
Art Unit 1743